DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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PURGED

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

August 27, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98-48

David M. Hurley
President and CEO
Novartis Nutrition Corp.
5320 West 23rd Street
St. Louis Park, MN 55416

Dear Mr. Hurley:

This letter is in reference to your firm's product, "Resource Renal Crème Beverage", which is being marketed and distributed as a "Dietary supplement for renal dialysis patients." This claim goes beyond a claim allowed under the Dietary Supplement Health and Education Act and evidences intended use to treat/mitigate renal disease.

Based on the claim made for this product, its intended use, and the targeted population, "Resource Renal Creme Beverage" is a drug [201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)] and a "new drug" [Section 201(p) of the Act]. Therefore, it may not be marketed in the United States without an approved new drug application (Section 505 of the Act).

This drug is also misbranded [Section 502(f)(1) of the Act] because the labeling fails to bear adequate directions for use. In addition, the labeling is false and misleading because it suggests that the product is safe and effective for its intended uses when, in fact, this has not been established [Section 502(a) of the Act].

This letter is not intended to be an all-inclusive review of all the claims made in your labeling and promotional literature for your product. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations. Federal agencies are advised of the issuance of all Warning letters about drugs and devices so they may take this information into account when considering the award of contracts.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply should be sent to Carrie A. Hoffman, Compliance Officer, at the address on the letterhead.

Sincerely,

James A. Rahto
Director
Minneapolis District

xc: Novartis AG
35 Lichtstraffc
Building 200/209
CH 4002
Basle Switzerland